UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTIONS IN LIMINE

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Plaintiffs Federal Trade Commission and the People of the State of New York by Letitia James, Attorney General of the State of New York, respectfully submit this Memorandum of Law in Opposition to Defendants' First, Second, and Third Motions in Limine (ECF Nos. 345, 348, 351).

I. INTRODUCTION

Defendants have moved in limine to preclude Plaintiffs from: (1) introducing evidence relating to a Warning Letter from the Food and Drug Administration ("FDA Warning Letter") (First Motion in Limine, ECF No. 345); (2) characterizing analyses of the Madison Memory Study as "post hoc" (Second Motion in Limine, ECF No. 348); and (3) introducing evidence related to Defendant Underwood's "personal finances" (Third Motion in Limine, ECF No. 351).

With respect to Defendants' First Motion in Limine, Plaintiffs do not agree with Defendants' arguments relating to the FDA Warning Letter but will not introduce evidence thereof, provided that Defendants do not first introduce such evidence or evidence relating to the June 13, 2018 letter attached as Exhibit 1 to the Declaration of Jaclyn Metzinger (ECF No. 346-1) (the "FDA Close-Out Letter"). Defendants' First Motion in Limine is therefore moot.

Defendants' Second Motion in Limine should be denied on at least two grounds. First, the motion ignores contrary evidence and raises factual disputes that cannot be resolved via a motion in limine: namely, whether certain analyses performed on data from the Madison Memory Study were planned from the outset, and how the results of such analyses should be interpreted according to relevant scientific standards. Plaintiffs submit that analyses not defined in the study protocol were performed, and that Defendants' interpretations of the results of those analyses were not consistent with relevant scientific standards. The jury must consider

Plaintiffs' and Defendants' respective positions on these issues, making them inappropriate for resolution on a motion in limine. Second, analyses not defined in a study protocol are known as "post hoc" analyses in the relevant scientific fields, as Defendants' own experts acknowledge. Defendants will suffer no unfair prejudice from, and the jury will not be misled or confused by, use of "post hoc" and similar terms. Defendants' Second Motion in Limine should be denied.

Defendants' Third Motion in Limine should also be denied. Defendant Underwood is the co-founder and President of each of the Corporate Defendants.[1] Evidence of Mr. Underwood's ownership interest in and compensation from the Corporate Defendants is relevant to his bias as a witness in this litigation and is not outweighed by any prejudice. Plaintiffs would not seek to introduce evidence of Mr. Underwood's personal finances unrelated to his involvement with the Corporate Defendants.

II. DEFENDANTS' FIRST MOTION IN LIMINE IS MOOT

Defendants seek to preclude Plaintiffs or their experts from introducing evidence or eliciting testimony relating to the FDA Warning Letter (listed on Plaintiffs' August 31, 2022 exhibit list (ECF No. 299-3) as PX 405) and Defendants' response thereto (listed on Plaintiffs' August 31, 2022 exhibit list (ECF No. 299-3) as PX 404). Although Plaintiffs do not concede the validity of any of Defendants' arguments in their First Motion in Limine, Plaintiffs agree not to introduce evidence or elicit testimony about the FDA Warning Letter (PX 405) or Defendants' response thereto (PX 404) at the jury trial.[2] Accordingly, Plaintiffs' First Motion in Limine is

[1] "Corporate Defendants" refers to Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC.

[2] Plaintiffs understand from Defendants' motion that Defendants would seek to introduce evidence or elicit testimony about the FDA Close-Out Letter only if testimony or evidence relating to the FDA Warning Letter were first introduced by Plaintiffs at trial. *See* Defs.' Mot. in Lim. to Preclude Pls. or Their Experts from Introducing Evid. Relating to the FDA Warning

moot and should be denied. *See, e.g.*, *EFG Bank AG, Cayman Branch v. AXA Equitable Life Ins. Co.*, No. 17-CV-4767, 2023 WL 7004232, at *1 (S.D.N.Y. Oct. 24, 2023) (denying motion in limine as moot in light of representation that the plaintiffs did not intend to introduce the evidence in question); *United States v. Daugerdas*, No. S3 09 CR. 581, 2011 WL 573587, at *2 (S.D.N.Y. Feb. 16, 2011) (holding that motions in limine were moot because plaintiff agreed not to use exhibits at trial).

III. DEFENDANTS' SECOND MOTION IN LIMINE SHOULD BE DENIED

Defendants seek to prevent Plaintiffs from referring to "'post hoc' analyses, 'after the fact' analyses, or similar characterizations" in describing analyses that were performed on data from the Madison Memory Study, contending that certain subgroup analyses were "planned from the beginning of the study" and thus, that references to "post hoc analyses" would be prejudicial and mislead or confuse the jury. Defs.' Mot. in Lim. to Preclude Pls. or Their Experts from Characterizing the Madison Memory Study Analyses as "Post Hoc" ("Defs.' Mem. in Supp. of 2d Mot. in Lim.") (ECF No. 350) at 3. Defendants' motion in limine is improper because it goes to the crux of disputes between the parties about whether certain analyses performed on data from the Madison Memory Study were planned from the outset, and how the results of such analyses should be interpreted according to relevant scientific standards. Such disputes are inappropriate for resolution on a motion in limine; they must be considered at trial. Further,

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Letter (ECF No. 347) at 2 (requesting that the FDA Close-Out Letter be allowed into evidence "if the Court finds that testimony and evidence relating to the [FDA] Warning Letter is admissible"). However, if Defendants seek to introduce evidence relating to the FDA Close-Out Letter in the absence of evidence of the FDA Warning Letter and the Court allows such evidence to be introduced, Plaintiffs may request that the FDA Warning Letter and Quincy's response thereto also be allowed into evidence to put the FDA Close-Out Letter in context.

Defendants will suffer no unfair prejudice from, and the jury will not be misled or confused by, the use of the challenged terms. The Court should deny Defendants' motion.

A. The Factual Disputes Defendants Raise Cannot Be Determined in Limine

Defendants' request to exclude the terms "post hoc," "after the fact," and similar terms from trial is tantamount to a request that the Court find, in limine, that certain analyses of Madison Memory Study data were planned from the outset of the study (where Plaintiffs contend that they were not), or that researchers may rely on analyses they decided to conduct after a study's results were known to support claims that an intervention is efficacious (Plaintiffs contend they may not). Those are issues for the jury to consider at trial and inappropriate for resolution on a motion in limine. *See, e.g.*, *SEC v. Dean*, No. 17-CV-139, 2019 WL 8683369, at *8 (S.D.N.Y. June 7, 2019) ("'[A] motion in limine should not be used to resolve factual disputes or weigh evidence'" (quoting *C & E Servs., Inc. v. Ashland Inc*., 539 F. Supp. 2d 316, 323 (D.D.C. 2008))); *FPP, LLC v. Xaxis US, LLC*, No. 14-CV-6172, 2017 WL 11456573, at *2 (S.D.N.Y. Mar. 16, 2017) (denying motion in limine that raised issues of fact for trial, not a "dispute that is appropriate for resolution on a motion in limine").

In their motion, Defendants point only to the self-serving testimony of their own witnesses in this litigation in support of their contention that "the record evidence plainly demonstrates" that the Madison Memory Study's "statistically significant results (specifically those in . . . AD8 0-1 and AD8 0-2 study populations)" were from analyses that were "planned from the beginning of the study." Defs.' Mem. in Supp. of 2d Mot. in Lim. (ECF No. 350) at 2. To begin with, the absence of documentary evidence pre-dating the completion of the Madison Memory Study that includes Defendants' subgroup analyses supports Plaintiffs' assertion that the subgroup analyses were not prespecified or planned from the beginning of the study.

Moreover, the Madison Memory Study Protocol, which was the only documentation of the statistical analysis planned for the study, does not specify any subgroups for analysis (nor does it include any reference to the AD8 scale at all, either in its discussion of inclusion and exclusion criteria or in its description of the intended analysis of results). *See* the accompanying Declaration of Andrew Wone dated Nov. 30, 2023 ("Wone Decl.") Ex. 1, Madison Memory Study Protocol (QUI-FTCNY-00068424); Wone Decl. Ex. 2, Tr. of Aug. 6, 2020 Dep. of Kenneth Lerner ("Lerner Dep. Tr.") at 48:9–49:25 (protocol set forth only documentation of statistical analysis plan); *see also* Graham Decl. Ex. B (ECF No. 308-2), Expert Report of Mary Sano ("Sano Affirmative Report") ¶¶ 56–57, 68–69, 73, 78; Graham Decl. Ex. F (ECF No. 308-6), Expert Report of Janet Wittes ("Wittes Affirmative Report") ¶¶ 33–35, 54, 78(b)–(c); Graham Decl. Ex. G (ECF No. 308-7), Resp. of Janet Wittes ("Wittes Rebuttal Report") ¶ 22. In fact, subjects with all possible AD8 scores were enrolled in the study. *See, e.g.*, Wone Decl. Ex. 2, Lerner Dep. Tr. at 64:23–25 (Q. "Were any participants excluded based on their AD8 score?" A. "No."), 149:7–150:5 (discussing study results for each AD8 score). Defendants' argument also ignores additional evidence that Plaintiffs have developed through discovery that supports that AD8 0–1 and 0–2 subgroups were not the Madison Memory Study's originally intended target population. *See* Pls.' Opp'n to Defs.' Mot. to Exclude Pls.' Experts (ECF No. 313) at 14–16 (collecting evidence). Defendants are incorrect in stating that "there is no evidence suggesting, much less demonstrating, that such analyses were 'post hoc,'" and they miss the point in criticizing Plaintiffs' experts for not knowing "when" the Madison Memory Study subgroup analyses were conducted. Defs.' Mem. in Supp. of 2d Mot. in Lim. (ECF No. 350) at 2–3. Exactly when the analyses were conducted is not material; whether the analyses were prespecified or preplanned is.

While post hoc analyses may have value in contexts that are irrelevant to this litigation, Plaintiffs' position is that such analyses cannot be used to support claims that an intervention is efficacious particularly where, as here, the documentary evidence that does exist shows that data were analyzed and reanalyzed until an indication of statistical significance was found. *See, e.g.*, Graham Decl. Ex. B (ECF No. 308-2), Sano Affirmative Report ¶¶ 38, 56–57; Graham Decl. Ex. F (ECF No. 308-6), Wittes Affirmative Report ¶¶ 33–35; Graham Decl. Ex. G (ECF No. 308-7), Wittes Rebuttal Report ¶ 22.

A motion in limine "'is not a proper vehicle for a party to ask the Court to weigh the sufficiency of the evidence to support a particular claim or defense.'" *Altruis Grp., LLC v. ProSight Specialty Mgmt. Co., Inc*., No. 21-CV-10757, 2023 WL 4784233, at *5 (S.D.N.Y. July 26, 2023) (quoting *Pavone v. Puglisi*, No. 08-CV-2389, 2013 WL 245745, at *1 (S.D.N.Y. Jan. 23, 2013)). Yet that is exactly what Defendants' motion asks the Court to do: weigh the sufficiency of the evidence in limine, before trial, on whether certain analyses performed on data from the Madison Memory Study were planned from the outset or developed post hoc, and how the results of any post hoc analyses should be interpreted according to relevant scientific standards. Defendants should not be allowed to sweep aside Plaintiffs' arguments and the evidence that Plaintiffs have developed in this manner. The factual disputes that Defendants' motion raises are for the jury to consider at trial.

B. Defendants Will Suffer No Unfair Prejudice; Nor Will the Jury Be Misled

Evidence may be excluded as unfairly prejudicial under Rule 403 "only when it tends to have some adverse effect upon a defendant *beyond* tending to prove the fact or issue that justified its admission into evidence." *United States v. Figueroa*, 618 F.2d 934, 943 (2d Cir. 1980) (emphasis added). Evidence cannot be excluded under Rule 403 "on the basis that, due to its

relevance, such evidence has a negative impact on a party's litigation position." *MBIA Ins. Corp. v. Patriarch Partners VIII, LLC*, No. 09-CV-3255, 2012 WL 2568972, at *11 (S.D.N.Y. July 3, 2012) (citing *George v. Celotex Corp*., 914 F.2d 26, 31 (2d Cir. 1990)). Plaintiffs' use of the term "post hoc" and similar terms is critical of Defendants' analysis and interpretation of study data, but neither unfairly prejudicial to Defendants nor confusing or misleading to the jury.

Analyses of subgroups not prespecified in a study protocol are, *by definition*, "post hoc" in nature. Graham Decl. Ex. B (ECF No. 308-2), Sano Affirmative Report ¶¶ 23–27, 34(a), 38, 57; Graham Decl. Ex. F (ECF No. 308-6), Wittes Affirmative Report ¶¶ 12, 33–35; *see also* Pls.' Opp'n to Defs.' Mot. to Exclude Pls.' Experts (ECF No. 313) at 14. Indeed, although their proposed testimony is objectionable in other ways, even Defendants' experts acknowledge that the term "post hoc" refers to analyses of study data that were not identified in study protocols or otherwise preplanned or prespecified prior to obtaining study results.[3] Here, subgroup analyses not prespecified in the Madison Memory Study Protocol are, by definition, post hoc analyses.

[3] *See, e.g.*, Tr. of Oct. 5, 2021 Dep. of Dr. Lee-Jen Wei at 97:21–98:1 (Q: "If a study . . . were to later conduct a subgroup analysis that was not identified in the protocol, would you consider that subgroup analysis to be post hoc?" A: "Yeah, you can name this post hoc analysis."); Tr. of Sept. 22, 2021 Dep. of Dr. David Schwartz at 204:18–205:6 (Q: "In that paragraph you state . . . , 'Typically, subgroup analyses are prespecified and planned prior to examination of the data.' Do you see that?" A: "I see that." Q: "Do you agree that prespecifying subgroup analyses increases transparency about what the researchers intended?" . . . A: "Yes. Broadly speaking, prespecified subgroup analyses does provide a clear sense of what the researchers intended to study, yes."); Tr. of Sept. 29, 2021 Dep. of Dr. Mindy Kurzer at 63:11–21 (Q: "Have you ever heard someone describe a change being made to an RCT as post hoc?" A: "Yes." Q: "And what is your understanding of what post hoc means in that context?" A: "Post hoc is -- my understanding of the use of the term 'post hoc' in this context is that it is analyses that are done that were not planned, preplanned, that were decided after the study was -- was complete."); Tr. of Oct. 20, 2021 Dep. of Dr. David Katz at 69:16–22 (Q: "And if a study were to later conduct a subgroup analysis that was not identified in the protocol, would you consider it to be post hoc?" A: "Generally that's correct." Q: "Should a protocol describe the statistical techniques that will be used to analyze the study data?" A: "In general, yes."). Excerpts from the transcripts cited in this footnote are attached to the accompanying Wone Declaration as Exhibits 3–6.

Experts in the relevant fields use the term "post hoc" for analyses that were not prespecified because they recognize that documenting all subgroups that researchers intend to analyze at the outset of a study protects the reliability of study results and prevents researchers from redefining the study population after seeing study data to claim findings of significance. *See* Graham Decl. Ex. B (ECF No. 308-2), Sano Affirmative Report ¶¶ 38, 56–57; Graham Decl. Ex. F (ECF No. 308-6), Wittes Affirmative Report ¶¶ 34–35. Conversely, failing to document all intended subgroups at the outset of a study increases the unreliability of study results by leaving researchers free to redefine the study population after the fact. *Id.* Defendants are incorrect in stating that Plaintiffs' use of the phrase "post hoc" in connection with Madison Memory Study analyses is "for pejorative purposes only." Defs.' Mem. in Supp. of 2d Mot. in Lim. (ECF No. 350) at 3. Instead, the term "post hoc" is part and parcel of substantive critiques that Plaintiffs have of Defendants' analysis and interpretation of the Madison Memory Study. The jury will not be misled or confused and Defendants will suffer no unfair prejudice under Rule 403 from the use of those terms at trial. *See, e.g.*, *Figueroa*, 618 F.2d at 943; *MBIA Ins. Corp.*, 2012 WL 2568972, at *11.

Because the motion raises factual disputes inappropriate for resolution in limine and there will be no unfair prejudice or misleading of the jury from the use of the term "post hoc" and similar terms, Defendants' Second Motion in Limine should be denied.

IV. DEFENDANTS' THIRD MOTION IN LIMINE SHOULD BE DENIED

Defendants' Third Motion in Limine should be denied because Defendant Underwood's ownership interest in and financial relationship to the Corporate Defendants, including his compensation therefrom, are relevant to his bias as a witness in this litigation. Plaintiffs would not seek to introduce evidence of Mr. Underwood's personal finances, net worth, or wealth as

distinct from his involvement with the Corporate Defendants. The Court should allow Plaintiffs to present evidence of Mr. Underwood's ownership interest in and financial relationship to the Corporate Defendants sufficient to establish Mr. Underwood's bias as a witness.

In cross-examining witnesses, "counsel . . . are entitled to very considerable latitude in inquiring into circumstances that may show bias on the part of the witness in favor of the party calling him." *LNC Invs., Inc. v. First Fid. Bank*, No. 92-CV-7584, 2000 WL 1182772, at *2 (S.D.N.Y. Aug. 21, 2000). "Proof of bias is almost always relevant because the jury, as finder of fact and weigher of credibility, has historically been entitled to assess all evidence which might bear on the accuracy and truth of a witness' testimony." *United States v. Abel*, 469 U.S. 45, 52 (1984). Accordingly, whether financial interest impacts a witness's credibility is a matter for the jury to resolve.

Courts routinely allow parties to present evidence of witnesses' financial relationship to and compensation from corporate defendants. Indeed, such evidence has been described as "highly probative" of bias in litigation and "not substantially outweighed by any prejudice." *Dyson Tech. Ltd. v. Maytag Corp.*, No. 05-CV-00434, 2007 WL 6599027, at *2 (D. Del. May 25, 2007). In *Dyson*, the company moved to exclude any evidence or argument concerning James Dyson's personal wealth and his compensation and return on investment from the Dyson parent company. Although the court agreed that evidence regarding Mr. Dyson's "personal wealth" would have "only marginal probative value" that would be "substantially outweighed by the prejudice" the company would suffer, the court specifically noted that Mr. Dyson's "compensation and return on investment" from the Dyson parent company would be highly probative of bias and not substantially outweighed by prejudice. *Id.* Similarly, while the court in *SynQor, Inc. v. Vicor Corp*. precluded evidence of the "personal wealth, income, and/or net

worth of fact witnesses," it explicitly noted that its ruling "does not preclude SynQor from showing the jury relevant evidence regarding the specific financial relationship between Mr. Vinciarelli [Vicor's principal and CEO] and Vicor, including specifically his history and ownership of Vicor, in order to establish bias." No. 2:14-CV-287, 2022 WL 7219272, at *6 (E.D. Tex. Oct. 7, 2022).[4]

Here, where Plaintiffs have represented that they will not seek to introduce evidence of Mr. Underwood's personal finances or wealth as distinct from his involvement with the Corporate Defendants, the result should be the same as in *Dyson* and *SynQor*. Mr. Underwood is not only the co-founder and President of each of the Corporate Defendants, but also Corporate Defendant Quincy Bioscience Holding Company, Inc.'s largest shareholder with a 33% stake in its stock. *See* Wone Decl. Ex. 7, Tr. of Aug. 21, 2020 Dep. of Mark Underwood at 37:13–20; Op. & Order Granting in Part and Den. in Part Defs.' Mot. to Dismiss (ECF No. 72) at 2. Evidence of these facts is highly probative of Mr. Underwood's bias as a witness, and not substantially outweighed by any prejudice. *Dyson*, 2007 WL 6599027, at *2; *see also SynQor*, 2022 WL 7219272, at *6; *Teva Pharms. USA*, 2019 WL 13244252, at *14. Plaintiffs should not be prevented from making use of such evidence for the purpose of establishing bias at trial.

The authorities that Defendants cite in support of their motion are not to the contrary. *Hermosillo v. County of San Bernadino* (cited in Defendants' memorandum in support of their third motion (ECF No. 352) at 3) did not involve testimony of an executive and shareholder of a corporate defendant, but rather individual defendants in a case involving alleged misconduct by

[4] Courts also allow the presentation of compensation evidence where relevant to possible bias for witnesses other than key executives or owners of a company. *See, e.g.*, *United States v. Teva Pharms. USA, Inc.*, No. 13-CV-3702, 2019 WL 13244252, at *14 (S.D.N.Y. July 1, 2019) ("any form of compensation physician[] [witnesses] receive from Teva can be used to show bias").

law enforcement. No. EDCV 15-00033, 2017 WL 5479645, at *3 (C.D. Cal. Feb. 16, 2017). *Smart Marketing Group, Inc. v. Publications International, Ltd*. ("*SMG*," also cited in Defendants' memorandum in support of their third motion (ECF No. 352) at 3) is inapposite too. No. 04 C 146, 2014 WL 625321, at *3 (N.D. Ill. Feb. 18, 2014). The motion in limine that Defendants cite arose after the *SMG* defendant's liability on a breach of contract claim had already been established and a new damages trial was ordered after an appeal of the original damages award. In the first trial, the *plaintiff's* principal (William Magarity) had testified that he sold his home; the *defendant* then moved to exclude evidence of "personal financial devastation" from the second damages trial on the grounds that Mr. Magarity's personal finances were irrelevant to the calculation of the plaintiff company's lost profits resulting from the defendant's breach of contract. It was in that context that the court excluded testimony about Mr. Magarity's personal financial devastation because it "appear[ed] designed merely to elicit sympathy from the jury." *SMG*, 2014 WL 625321, at *3. *SMG's* facts are not analogous to the facts in this case, where Mr. Underwood's ownership interest in and financial relationship to the Corporate Defendants are relevant to his bias as a witness.

Accordingly, Defendants' Third Motion in Limine should be denied.

V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' First Motion in Limine (ECF No. 345), Second Motion in Limine (ECF No. 348), and Third Motion in Limine (ECF No. 351).

Respectfully submitted,

Dated: November 30, 2023

FEDERAL TRADE COMMISSION

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of November, 2023, I have caused service of the foregoing Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions in Limine to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: November 30, 2023

/s/ Tiffany M. Woo
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